510(k) Summary

RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport™ JUN 22 2011

1. **Submitter:** Smith & Nephew, Inc.
   970 Lake Carillon Drive, Suite 110
   St. Petersburg, FL 33716

2. **Contact:** Laura D. Reynolds, RAC
   Director Regulatory Affairs
   727-329-7702

3. **Date Prepared:** May 16, 2011

4. **Device Name:** RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport
   Classification Name/Code: Powered Suction Pump / 21 CFR 878.4780
   Product Classification: Class II
   Product Code: OMP

5. **Predicate Device Information:**

   a. RENASYS-F NPWT Foam Dressing kits
   b. Smith & Nephew, Inc.
   c. 510(k) # K082211

   d. Versatile 1 Wound Vacuum System
   e. BlueSky Medical (Smith & Nephew, Inc.)
   f. 510(k) #K042134

6. **Device Description:**

With the exception of the Softport™ assembly, there are no changes to the components in the currently marketed foam and gauze wound dressing kits. The RENASYS™ Foam and Gauze Wound Dressing Kits with Softport consist of the following components:

Foam Kits: Polyurethane foam wound filler, a Softport assembly and transparent film drape. The foam kits are supplied sterile, single use and are offered in three sizes: small, medium and large.

Gauze Kits: Antimicrobial gauze wound filler, a Softport assembly, non-adherent wound contact layer, transparent film drape, saline bullet, No Sting Skin Prep and wound ruler. The Gauze kits are offered in four sizes: small, medium, large and extra-large. The individual components of the kit are packed sterile and kitted in a non-sterile kit package. The kit is single use.

The Softport assembly attaches to an exudate canister to carry exudate from the wound. The kits are designed specifically for use with the RENASYS EZ / EZ Plus and RENASYS GO negative pressure wound therapy devices and canisters which have been cleared under 510(k) numbers K091470, K102001 and K083375.

7. Intended Use:

The RENASYS™ Foam and Gauze Wound Dressing Kits with Softport are intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

8. Summary of Non-Clinical Testing:

The RENASYS Foam and Gauze Wound Dressing Kits with Softport were evaluated under a number of verification and validation tests to ensure performance requirements were met.

- The Softport shall serve as a conduit between RENASYS EZ and RENASYS GO NPWT therapy devices and NPWT wound dressings by transmitting negative pressure and collecting exudate flows.
- The Softport shall function throughout the recommended maximum elapsed time of 72 hours between dressing changes.
- The Softport will continue to serve as a conduit between RENASYS EZ and RENASYS GO NPWT therapy devices and NPWT wound dressings by transmitting negative pressure and collecting exudate flows when compressed at its terminal end (atop the wound dressing).
- The Softport shall incorporate a controlled leak path that does not contribute to RENASYS EZ and RENASYS GO NPWT therapy devices false blockage or leak alarms.

With the exception of the Softport™ assembly, none of the components in the currently marketed foam and gauze dressing kits have changed. Biocompatibility on all components has been successfully completed in accordance with applicable parts of ISO 10993.

The following biocompatibility testing for the Softport assembly has been successfully completed per applicable parts of ISO 10993:

- Cytotoxicity
- Skin Irritation
- Skin Sensitization

9. Conclusion:

The RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport are substantially equivalent in design, materials, technology, function and intended use to the predicate devices named above. Verification and validation testing has been conducted to demonstrate the device is safe and effective for the intended use.

Renasys Foam and Gauze NPWT Wound Dressing Kits with Softport Device Comparison Table

Device:	Smith & Nephew New Device:	Predicate Device:	Predicate Device:
Name:	RENASYS™ - Foam and Gauze Wound Dressing Kits with Softport	RENASYS-F NPWT Foam Dressing kit	Versatile 1 Wound Vacuum System (including gauze wound dressing kits)
510(k):	K110647	K082211	K042134
Manufacturer:	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Blue Sky Medical (Smith & Nephew, Inc.)
Intended Use:	The RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport are Intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	Foam dressing kits are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy systems to deliver negative pressure to the wound. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. NPWT is appropriate for use on the following wounds: • Pressure ulcers • Diabetic / neuropathic ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Explored fistulas • Skin flaps and grafts	Indicated for patients who wound benefit from a suction device particularly as the device may promote wound healing.
Materials:	**Wound Filler:**		

	Hydrophobic, Polyurethane foam or Antimicrobial Gauze **Softport assembly:** Polyurethane film, 3-D knit polyester fabric, Polyurethane foam, Non-woven polyester, Polyurethane drape with adhesive coating, Polyurethane drape	Hydrophobic, Polyurethane foam Silicone drain PVC Tube Polyurethane drape	Antimicrobial Gauze Silicone drain PVC Tube Polyurethane drape
Single-use or Reusable:	Single-use	Single-use	Single-use
Method of Sterilization:	Ethylene Oxide Or Individual kit components individually sterilized by Ethylene Oxide or Gamma Irradiation.	Ethylene Oxide	Individual kit components individually sterilized by Ethylene Oxide or Gamma Irradiation.
Biocompatibility:	All components comply with ISO 10993	All components comply with ISO 10993	All components comply with ISO 10993
Packaging:	Components packaged loose in a pouch then sterilized Or Pre-packaged and sterilized and placed in package as a convenience kit	Components packaged loose in a pouch then sterilized	Pre-packaged and sterilized and placed in package as a convenience kit

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Laura Reynolds
Director, Regulatory Affairs
970 Lake Carillon Drive
St. Petersburg, Florida 33716

JUN 2 2 2011

Re: K110647
Trade/Device Name: RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP, BTA
Dated: June 13, 2011
Received: June 14, 2011

Dear Ms. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110647

Device Name: RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport™

Indications for Use:

The RENASYS™ Foam and Gauze NPWT Wound Dressing Kits with Softport are intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Daniel Krause for MKM Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices